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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/640,990	08/18/2000	Riley Rees	3572-0101P	6659
23535	7590	02/13/2004	EXAMINER	
MEDLEN & CARROLL, LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105			NAFF, DAVID M	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/640,990	REES, RILEY	
	<b>Examiner</b>	<b>Art Unit</b>	
	David M. Naff	1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-7,10,11 and 13-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,10,11 and 13-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/22/03</u> . | 6) <input type="checkbox"/> Other: _____  |

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***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for  
5 continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/26/03 has been entered.

The amendment of 11/26/03 amended claims 1, 2-6, 10, 11, 14, 16  
10 and 20, and canceled claims 2 and 22. Claims 8, 9, 12 and 21 have previously been canceled.

Claims examined on the merits are 1, 3-7, 10, 11 and 13-20 which are all claims in the application.

Document 14 on form PTO-1449 has been lined through since it was  
15 previously listed on form PTO-892. Documents 5 and 29 have not been considered and lined through since a copy of each document was not included in the Information Disclosure Statement of 9/22/03.

The substitute specification of 11/13/02 has been entered.

The text of those sections of Title 35, U.S. Code not included in  
20 this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 103***

Claims 1, 3-7, 10, 11 and 13-20 are rejected under 35 U.S.C.  
103(a) as being unpatentable over Rees et al (6,197,330 B1),  
(5,972,332), (6,440,452 B2) or (6,399,898 B2) in view of Dionne et al  
25 (5,786,216) and Shapiro et al (6,425,918 B1).

Claim 1 and claims dependent thereon require providing an unsealed enclosure, introducing a solid support material into the unsealed enclosure, sealing the enclosure and injecting cells into the sealed enclosure where the cells attach to the support. Claim 10 and  
5 claims dependent thereon require the same procedure except that instead of injecting cells into the enclosure, the sealed enclosure containing the support is immersed in a culture of cells, and the cells migrate into the sealed enclosure and attach to the support.

Rees et al ('330), ('332), ('452) and ('898) disclose attaching  
10 cells to a solid support, placing the cell-containing solid support into an enclosure and sealing the enclosure.

Dionne et al disclose injecting cells into a capsule which may contain a hydrogel support. See the abstract and col 4, lines 24-26.

Shapiro et al disclose implanting a sponge support into a patient  
15 and then after blood vessels have invaded the support, injecting cells into the support (col 5, lines 15-25).

The method disclosed by the Rees et al patents is the same as presently claimed except that in the claims the cells are attached to the support by injecting cells into the enclosure after sealing.

20 It would have been a matter of obvious choice depending on individual preference and convenience to modify the method of the Rees et al patents by putting the support into the enclosure, sealing the enclosure and injecting cells into the enclosure to attach the cells to the support in view of Dionne et al injecting cells into a capsule  
25 that may contain a support and Shapiro et al injecting cells into a

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sponge support after the support has been implanted in a patient.

Dionne et al and Shapiro et al clearly suggest injecting cells after the enclosure of Rees et al is sealed to attach cells to the support as an alternative to attaching cells to the support before the support is put in the enclosure. No unexpected result is apparent. The limitations of the dependent claims are disclosed by Rees et al or would have been obvious in view of conditions disclosed by Dionne et al and Shapiro et al.

#### **Response to Arguments**

Applicant urges that the Rees et al patents do not teach sealing the enclosure and then injecting cells. However, in view of Dionne et al injecting cells into a closed capsule containing a support and Shiparo et al injecting cells into support after the support is implanted in a patient, the alternative of injecting cells after the enclosure of Rees et al is sealed is clearly obvious.

#### **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5        Claims 1, 3-7, 10, 11 and 13-20 are rejected under the judicially  
created doctrine of obviousness-type double patenting as being  
unpatentable over claims 1-17 of U.S. Patent No. 6,197,330 B1 or  
claims 1-6 of U.S. Patent No. 5,972,332 or claims 1-22 of U.S. Patent  
No. 6,440,452 B2 or claims 1-21 of U.S. Patent No. 6,299,898 B2 in  
10 view of Dionne et al and Shapiro et al.

For the reasons set forth above in the 103 rejection, it would  
have been obvious in view of Dionne et al and Shapiro et al to inject  
cells into the enclosure of the claims of patent ('330), ('332),  
('452) or ('898) after the enclosure has been sealed to attach cells  
15 to the support in the enclosure.

Any inquiry concerning this communication or earlier  
communications from the examiner should be directed to David M. Naff  
whose telephone number is 571-272-0920. The examiner can normally be  
reached on Monday-Friday 9:30-6:00.

20        If attempts to reach the examiner by telephone are unsuccessful,  
the examiner's supervisor, Mike Wityshyn can be reached on 571-272-  
0926. The fax phone number for the organization where this  
application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff  
Primary Examiner  
Art Unit 1651

DMN  
2/7/04